

AGRICULTURE COMMITTEE

Seventh Report

**VITAMIN B6:
THE GOVERNMENT'S DECISION**

Report, Appendix and Proceedings of the Committee

*Ordered by The House of Commons to be printed
30 July 1998*

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The Agriculture Committee is appointed under Standing Order No 152 to examine the expenditure, administration and policy of the Ministry of Agriculture, Fisheries and Food and of associated public bodies.

The Committee consists of 11 Members. It has a quorum of three. Unless the House otherwise orders, all Members nominated to the Committee continue to be members of it for the remainder of the Parliament.

The Committee has power:

- (a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;
- (b) to appoint specialist advisers either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;
- (c) to communicate to any other committee appointed under the same Standing Order (or to the Committee of Public Accounts, the Deregulation Committee and the Environmental Audit Committee) its evidence and any other documents relating to matters of common interest; and
- (d) to meet concurrently with any other such committee for the purposes of deliberating, taking evidence, or considering draft reports.

The Committee was nominated on 14 July 1997.

The following are members of the Committee:

Mr Peter Luff (Chairman)

Mr David Curry	Ms Sally Keeble
Mr Andrew George	Mr Paul Marsden
Mr John Hayes	Mr Austin Mitchell
Mr Alan Hurst	Mrs Diana Organ
Ms Fiona Jones	Mr Mark Todd

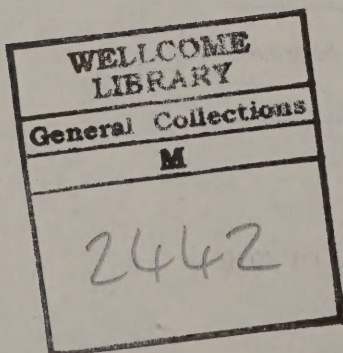


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2. Our Report was published towards the end of the Government's period of public consultation on the draft Vitamin B6 or Food Regulations, incidentally on the consultation on Vitamin B6 in dietary supplements. That consultation ended on 20 June. On 27 June there was a 30-minute Government debate in the House on Vitamin B6 in the main, of Sir Keith Joseph. Though this was not a debate specifically on the Report, our conclusions and recommendations were clearly informed by the debate, and we were pleased to note that, of the seven backbench Members who spoke, five, from all three main parties, were supportive of the Committee's view, while two spoke with the Government's proposals. A number of Early Day Motions on the subject have been tabled. The one which has attracted most cross-party signatures, tabled on 27 November 1994, called for the Minister for Food Safety, Mr Jeff Rooker MP, Secretary of State at MAFF, to ask COT and the FAC to review their advice. As at 29 July, it had been signed by 178 Members. When considering how to proceed in relation to Vitamin B6, therefore, Ministers have been in the fortunate position of having the views of a select committee and of a large number of other Members of the House on record, in addition to the responses to their public consultation exercise.

3. On 30 July, the Government announced its decision in relation to vitamin B6, in a Written Answer. Sir Ron Davies MP, the Minister of Agriculture, Fisheries and Food, said that:

"The Government has now completed its consideration of the response to the consultation exercise on the proposed controls on dietary supplements containing vitamin B6. Copies of the responses received have been deposited in the Library. We have also deposited copies of the responses received to the consultation by the Medicines Commission. A number of suggested proposals on controls on vitamins and minerals containing vitamin B6.

The Government has taken full account of the Agriculture Select Committee's report on vitamin B6 and has made its response public. (The decision on when and how this is published is a matter for the Committee.)

The Government's acceptance of the science remains that of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and our advice to the public will continue to reflect this. However, we accept that there is a case for delaying any action on vitamin B6 until the new Expert Committee on Vitamins and Minerals has completed its consideration of the wider issue of the principles on which controls for ensuring the safety of vitamins and mineral supplements and under what law can be based. This should take between eighteen months and two years, in view of the fact we have concluded that a decision on regulation on the level of vitamin B6 in dietary supplements should be delayed until after the Expert Committee on Vitamins and Minerals.

¹ This report from the Agriculture Committee, Volume 1997-98, paragraph 10.

² *ibid.*, 20 June 1994, col. 995-996.

³ *ibid.*, 27 June 1994, col. 996-997.

⁴ *ibid.*, 29 July 1994, col. 179.

SEVENTH REPORT

The Agriculture Committee has agreed to the following Report:

VITAMIN B6: THE GOVERNMENT'S DECISION

1. On 23 June 1998 we published our Fifth Report of this Session, on vitamin B6¹. That Report set out our opposition to the Government's proposals to place restrictions on the levels of vitamin B6 in dietary supplements, in line with advice which Ministers had received from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Food Advisory Committee (FAC). A full explanation of the background to these proposals, and of the scientific evidence of the toxicity of vitamin B6 on which they were based, is given in that Report.

2. Our Report was published towards the end of the Government's period of public consultation on its draft Vitamin B6 in Food Regulations, implementing the restrictions on vitamin B6 in dietary supplements. That consultation ended on 26 June. On 24 June there was a 90-minute adjournment debate in the House on vitamin B6 in the name of Mr Keith Simpson. Though this was not a debate specifically on our Report, our conclusions and recommendations clearly informed the debate, and we were pleased to note that, of the seven backbench Members who spoke, five, from all three main parties, were supportive of the Committee's view, while two agreed with the Government's proposals². A number of Early Day Motions on this subject have been tabled. The one which has attracted most cross-party signatures, tabled on 27 November 1997, called for the Minister for Food Safety, Mr Jeff Rooker MP, Minister of State at MAFF, to ask COT and the FAC to review their advice³. As at 29 July, it had been signed by 178 Members. When considering how to proceed in relation to vitamin B6, therefore, Ministers have been in the fortunate position of having the views of a select committee and of a large number of other Members of the House on record, in addition to the responses to their public consultation exercise.

3. On 30 July, the Government announced its decision in relation to vitamin B6. In a Written Answer, Rt Hon Nicholas Brown MP, the Minister of Agriculture, Fisheries and Food, said that:

"The Government has now completed its consideration of the responses to the consultation exercise on the proposed controls on dietary supplements containing vitamin B6. Copies of the responses received have been deposited in the Library. We have also deposited copies of the responses received to the consultation by the Medicines Control Agency on its parallel proposals on controls on licensed medicines containing vitamin B6.

The Government has taken full account of the Agriculture Select Committee's report on vitamin B6 and has made its response today. (The decision on when and how this is published is a matter for the Committee.)

The Government's assessment of the science remains that of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment's (COT) and our advice to the public will continue to reflect this. However, we accept that there is a case for delaying any action on vitamin B6 until the new Expert Group on Vitamins and Minerals has completed its consideration of the wider issue of the principles on which controls for ensuring the safety of vitamin and mineral supplements sold under food law can be based. This should take between eighteen months and two years. In view of this we have concluded that a decision on legislation on the level of vitamin B6 in dietary supplements should be deferred until after the Expert Group has produced its report"⁴.

¹ Fifth Report from the Agriculture Committee, Session 1997-98, *Vitamin B6*, HC 753

² *HC Deb*, 24 June 1998, cols 984-1006

³ Early Day Motion No. 350, *Safety of Vitamin B6 Supplements*

⁴ *HC Deb*, 29 July 1998, col 470w

On the same day, the Government provided us with their Reply to our Fifth Report. The content of this Reply extends rather wider than the Written Answer, covering as it does issues relating to the Expert Group on Vitamins and Minerals which we had raised in our Report. We publish the Government's Reply, in full, as an Appendix to this Report.

4. The Government is unable to accept our recommendation that the 10mg daily limit is unnecessary, and maintains that its advice to consumers will be that their daily intake should not exceed 10mg other than on professional advice. However, the Government has decided to defer the introduction of any regulatory restriction on the level of vitamin B6 in dietary supplements until the Expert Group on Vitamins and Minerals has reported the results of its wider review of the safety of dietary supplements. The Expert Group's report is expected in eighteen months to two years time. **While we hold fast to our opinion that there is no evidence that intakes of vitamin B6 below 200 mg a day have any harmful effect, we welcome the flexibility which the Government has shown in responding to our Report and the other representations which have been made to it on this issue. It must be right for the Government to defer its decision until the Expert Group has reported on the wider issues. We also welcome the Government's favourable response to our recommendation that the industry and consumers should be able to nominate independent experts in nutrition and toxicology for appointment as full members of the Group.**

APPENDIX

GOVERNMENT'S RESPONSE TO THE AGRICULTURE SELECT COMMITTEE REPORT ON VITAMIN B6

Introduction

The Government is grateful to the Agriculture Select Committee for producing its report on Vitamin B6 so promptly. This memorandum represents our response to recommendations and conclusions of the report which are set out below together with our comments.

It is our view that the doubts concerning the 1987 Dalton and Dalton study are so serious that it is scientifically unjustifiable to use them as a basis for establishing a lowest observed effect level in relation to vitamin B6. (paragraph 20)

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) have always acknowledged that the Dalton and Dalton study has some methodological deficiencies but in the light of other supporting data it concluded that it would be unwise to ignore this evidence. It is not alone in this view: the EU Scientific Committee for Food along with some other European expert committees have taken account of this study when reviewing the safety of vitamin B6. The Government continues to have complete confidence in the COT's analysis of the scientific data on the safety of vitamin B6. It follows that it is unable to accept the Select Committee's views on this issue.

In relation to dietary supplements, the Government should withdraw its proposed draft regulations to limit the level of vitamin B6 per daily dose to 10mg. (paragraph 22)

We recommend that the Government should seek to introduce a voluntary limit, pending the report of the Expert Group on Vitamins and Minerals, with the industry, of 100mg per daily dose. All dietary supplements containing vitamin B6 should display a clear warning that intakes above this level may carry health risks, particularly if taken over an extended period. No legislation should be considered until the Expert Group has reported. (paragraph 24)

The Government accepts the Select Committee's view that action on vitamin B6 should not be taken in isolation but in the context of the wider review of the safety of dietary supplements which is to be undertaken by the Expert Group on Vitamins and Minerals. The Government recognises that the Expert Group will be considering the establishment of principles on which controls for ensuring the safety of vitamin and mineral supplements can be based.

In the light of these considerations, and the scientific advice of the COT, we do not consider that there is a basis for a voluntary limit of 100mg per daily dose, nor for warnings on the basis proposed by the Select Committee. But we have concluded that a decision on legislation on the level of vitamin B6 in dietary supplements should be deferred until after the Expert Group has produced its report. In the meantime, the Government's advice to consumers is that their daily intake of vitamin B6 from supplements sold under food law should not exceed more than 10mg per day other than on professional advice.

The evidence on the efficacy of vitamin B6 is inconclusive, and many consumers may experience a placebo effect rather than any actual health benefit. Nevertheless, such people are perfectly entitled to make such choices themselves, so long as they are provided with sufficient information to avoid the potential health risks of high levels of intake, and so long as dietary supplements do not make medicinal claims. These issues should have no bearing on the toxicological assessments of the safety of vitamins and minerals, whether in the case of vitamin B6 or in the case of the wider review of dietary supplements to be undertaken by the new Expert Group on Vitamins and Minerals. We trust that the unfortunate row

which has taken place over vitamin B6 will act as a constant reminder to that group of the need to base its recommendations and advice on sound and substantiated scientific knowledge, and adherence to a clear definition of the role and limits of Government intervention in this area as it recommends and Parliament agrees. (paragraph 25)

The Select Committee will recall that the decision to review the safety of vitamin B6 was prompted by concerns expressed by the Consumers' Association. The Committee will also recall that in its memorandum to the Select Committee (Appendix 38 of the Committee's report) the Consumers' Association noted that there is a lack of consumer awareness about the possible side effects of some vitamins, including vitamin B6. It also reported research that indicated only 26% of supplement users considered them to be foods while 40% regarded them as medicines. Almost 90% considered that supplements should be tested for safety. There was a general expectation that foods were regulated and wouldn't be on the market if they were dangerous.

The Government agrees that there is a delicate balance to be drawn in this and other areas between regulation to protect the public and the desire to determine such issues on the basis of personal choice. It is for this reason that the Government has accepted the Select Committee's recommendation that action on vitamin B6 should be deferred pending the report of the Expert Group on Vitamins and Minerals.

We would ... urge that the Expert Group on Vitamins and Minerals be asked to produce recommendations for a framework for deciding whether regulation of dietary supplements is necessary at all, or whether consumer advice is sufficient. (paragraph 19)

The terms of reference of the Expert Group on Vitamins and Minerals are to:

- *establish principles on which controls for ensuring the safety of vitamin and mineral supplements sold under food law can be based;*
- *review the levels of individual vitamins and minerals associated with adverse effects;*
- *recommend maximum levels of intakes of vitamins and minerals from supplements if appropriate;*
- *report to the Food Advisory Committee.*

The Government considers that these terms of reference do not place the Expert Group under any obligation to establish principles that would result in limits on the level of all vitamins and minerals in supplements sold under food law. It is for the Food Advisory Committee or, if it is established by the time the Group reports, the Food Standards Commission, to consider whether, in the light of the scientific advice provided by the Expert Group, changes to the regulation of dietary supplements or their labelling, should be recommended to Government.

We recommend that, to assist in avoiding any repeat of the vitamin B6 controversy, consumer and industry interests should be able to nominate one or two independent scientific experts in nutrition and toxicology for appointment as full members of the Group. (paragraph 26)

Membership of the Group already includes independent scientific experts in nutrition and toxicology. The group also includes observers nominated by industry, complementary medicine and consumer interests, three of whom are qualified scientists. It has always been envisaged that they will be able to participate in the work of the group, rather than simply observe its proceedings. Industry, complementary medicine and consumer interests will also be kept informed of the Group's work. Nevertheless, the Government sees merit in the Select Committee's recommendation and will be inviting consumer and industry interests to nominate independent experts.

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

THURSDAY 30 JULY 1998
[Afternoon sitting]

Members present:

Mr Peter Luff, in the Chair

Mr Andrew George
Mr Alan Hurst
Mr Paul Marsden

Mr Austin Mitchell
Mr Mark Todd

The Committee deliberated.

Draft Report [Vitamin B6: The Government's Decision], proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 4 read and agreed to.

Resolved, That the Report be the Seventh Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the following Paper be appended to the Report: Government's Response to the Agriculture Select Committee Report on Vitamin B6.—(*The Chairman.*)

Ordered, That the Appendix to the Report be reported to the House.—(*The Chairman.*)

[Adjourned to a day and time to be fixed by the Chairman.]

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